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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,233	09/17/2003	Gilles R. G. Monif	1365-001	5452
23485	7590	06/02/2004	EXAMINER	
JINAN GLASGOW P O BOX 28539 RALEIGH, NC 276118539			SWARTZ, RODNEY P	
		ART UNIT		PAPER NUMBER
		1645		

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/665,233	MONIF, GILLES R. G.
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 March 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
  - 4a) Of the above claim(s) 7-14 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) 1-6 is/are objected to.
- 8) Claim(s) 1-14 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                         |                                                                             |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.                                               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                         | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

1. Applicant's Response to Restriction Requirement, received 17 March 2004, is acknowledged. Applicant elects, without traverse, Invention I, claims 1-6, drawn to method of immunizing hosts, classified in class 424, subclass 9.1.

Claims 7-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-6 are under consideration.

### **Specification**

3. The disclosure is objected to because of the following informalities:

Page 1, line 15, "portal infection" should be "portal of infection",

Page 2, line 2, what is meant by "The target organ is the gastrointestinal disease"?

Page 2, line 17, it is unclear what is meant by "was being serial bleed",

Page 3, line 16, "strain" should be "strains",

Page 5, line 7, it is unclear what is meant by "graph relatively equivalent",

Page 11, line 7, what are the "pending publications"; line 15, "37°C" should be "37°",

Page 11, line 13, recites "S35 Methionine" while page 13, line 13 recites "35S methionine", consistent nomenclature should be utilized,

Page 13, lines 4 and 10, "37°C" should be "37°",

Page 14, line 6, "37°C" should be "37°",

Page 15, line 20, it is unclear what is meant by "graph relatively equivalent,

Appropriate correction is required.

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### **Drawings**

4. Figure 4 is objected to under 37 CFR 1.83(a) because it fails to show individual attachment of strains B, E, and F as described in the specification, page 16, lines 5-6. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. Figure 6 is objected to under 37 CFR 1.83(a) because it fails to show individual attachment of strains B, E, and F as described in the specification, page 16, lines 17-18. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### **Claim Objections**

6. Claims 1-6 are objected to because of the following informality: the abbreviation "MAP" should be spelled out at its first usage. Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to immunizing a host "organism" by administering an "organism". It is unclear what are the metes and bounds of "organism" because it is utilized both as a host and as the immunizing agent. Claims 2-6 depend from claim 1, but do not clarify the issue.

Claim 1, step b, recites that the organism is to be administered in an immunizing "manner". It is unclear what is meant by this term "immunizing manner". Claims 2-6 depend from claim 1, but do not clarify the issue.

10. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – oral immunization of a host animal against gastrointestinal, mucosally invasive *Mycobacterium avium* subspecies *paratuberculosis*

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comprising providing an enteric, mucosally adherent, nonsystemically invasive

*Mycobacterium avium* subspecies *paratuberculosis* organism and orally administering said organism to a host animal in an immunizing dose and manner.

The state of the prior art concerning oral immunization using *Mycobacterium* in animal models and humans is known. However, the success of the *in vivo* administration is dependent upon experiments *in vivo*, and do not necessarily correlate with merely cell attachment studies *in vitro*.

The amount of direction or guidance present – the instant specification provides no examples of the claimed method, merely *in vitro* attachment studies of live strains of *Mycobacterium avium* subspecies *paratuberculosis* using intestinal explants from normal calves. The instant specification provides insufficient guidance into what is an “immunizing” dose nor what is an “immunizing” manner. The instant specification provides no examples of nonprotein denatured killed organisms as vaccines.

Thus, the lack of guidance and examples in the instant specification constitutes merely an invitation to experiment in light of the quantity of experimentation necessary to determine the dose of vaccine required, the composition of vaccine required, and how to administer the vaccine to result in immunization which is effective against infection with *Mycobacterium avium* subspecies *paratuberculosis*.

### **Conclusion**

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

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June 1, 2004